National Cancer Institute (NCI)
Knowledge Acquisition Session Report

KA Session Date: Wed, Dec 3, 1997 **Session Time:** 11:00 A.M.

Session Topic: Clinical Trial Research Nurse

Knowledge Engineers: Lisa Mantock, ScenPro (Lead); Jennifer Brush, UTA; Christine DiNunzio, UTA; Meg Gronvall, Oracle

Organization: Lombardi Cancer Center

Session Location: Georgetown University Hospital, Washington, DC

Type of Session:

_____ Interview __X__ Task Analysis _____ Scenario Analysis
_____ Concept Analysis _____ Observation _____ Structured Interview
_____ Other: Tape

Documentation:

General Topic Area

Research Nurse roles and responsibilities

Session Goals

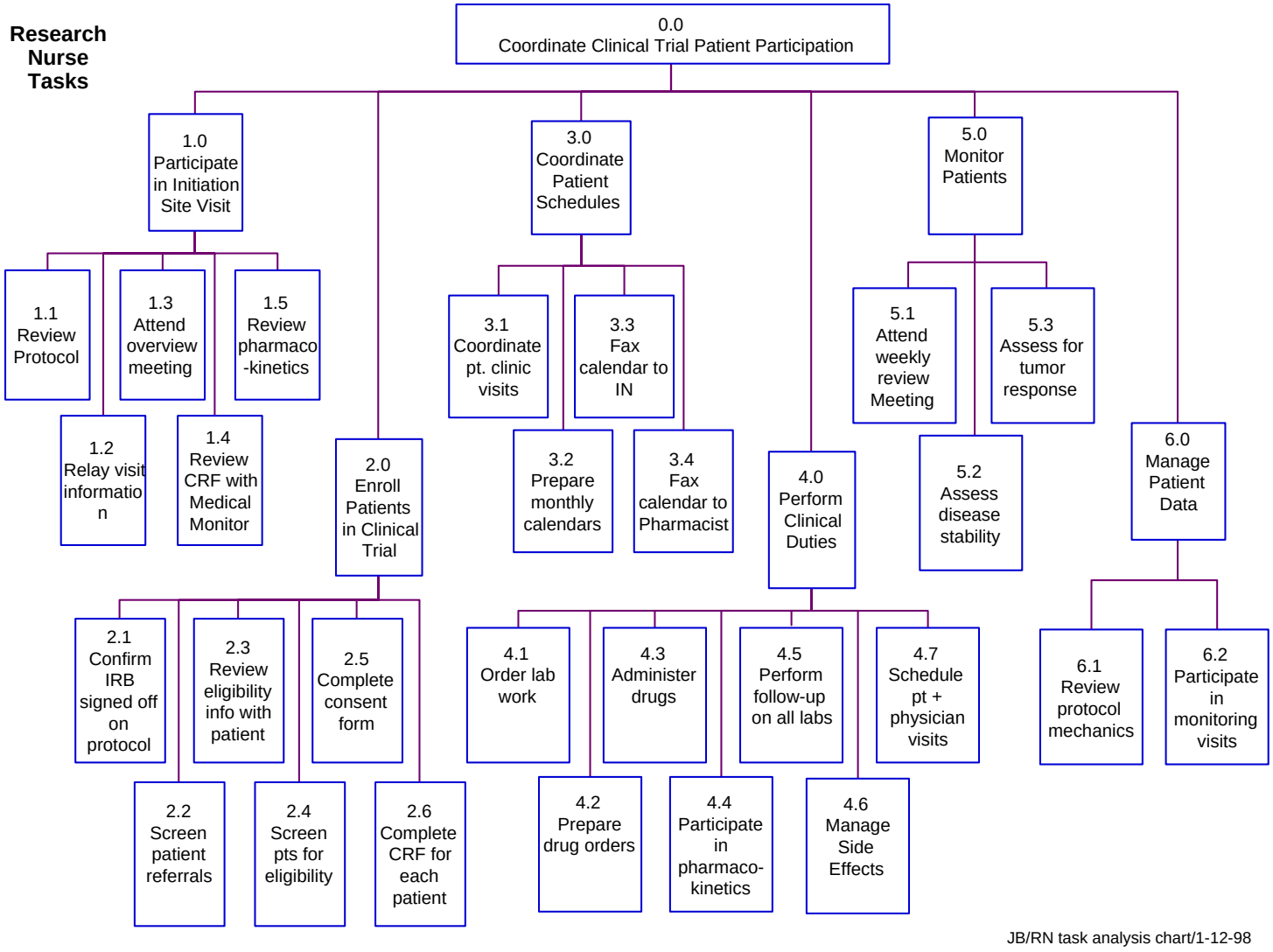
- Overview of key performers work process
- Identification of Research Nurse tasks and task attributes

Output Goals

- Hierarchical Task Analysis
- Entries for Domain Dictionary
- Optional - Initial Concept Identification

Report Summary

Liz Ness is a Phase I Clinical Trials Research Nurse at the Lombardi Cancer Center (LCC), Georgetown University, Washington DC. Her primary responsibilities include: participating in drug sponsor Initiation Site visits, enrolling patients in clinical trials, coordinating patient schedules, performing clinical duties, monitoring patients, and managing patient data. The task analysis report that follows was compiled from information gathered during an initial interview session.



Tasks

1.0 Participate in Initiation Site Visit

Goal: Familiarize Research Nurse with the mechanics, reporting and pharmacokinetic requirements for clinical trials held at the Lombardi Cancer Center (LCC).

1.1 read clinical trial protocol

1.2 communicate initiation site visit information to pharmacist, research assistant and data manager

- 1.2.1 provide time
- 1.2.2 provide day
- 1.2.3 provide location
- 1.2.4 provide name of drug sponsor
- 1.2.5 provide information regarding trial goals and constraints

1.3 attend overview meeting

1.4 review Case Report Form (CRF) with medical monitor

- 1.4.1 clarify patient & drug data reporting requirements

1.5 review pharmacokinetics with medical monitor & pharmacist
    1.5.1 clarify drug ordering and delivery
    1.5.2 clarify drug mixing
    1.5.3 clarify drug stability data
    1.5.4 clarify drug availability
    1.5.5 clarify sample processing
        1.5.5.1 temperature of storage
        1.5.5.2 shipment method

2.0 Enroll patient in clinical trial

Goal: Maintain patient accrual as outlined in the Phase I submission.

Constraint: Lack of eligible patients at internal facility. Inability to locate eligible patients at external facilities.

2.1 confirm Internal Review Board (IRB) has signed off on protocol
2.2 screen patient referrals
2.3 review trial eligibility information with patient
2.4 screen patients
    2.4.1 interview patient
    2.4.2 schedule patient for initial diagnostic screenings
        2.4.2.1 order labs
        2.4.2.2 schedule CAT scan
        2.4.2.3 perform baseline screening tests
    2.4.4 review lab findings with PI
    2.4.5 determine patient eligibility
2.5 complete patient consent form
    2.5.1 review consent information with patient
    2.5.2 confirm patient understanding of trial
    2.5.3 have patient or patient family member/representative sign form with witness
2.6 complete initial Case Report Form for each patient

3.0 Coordinate patient schedules

Goal: Make efficient use of patient and clinic staff time. Ensure patients care is administered according to the protocol submitted.

Constraints: Drug availability, staff and patient scheduling constraints.

3.1 coordinate clinic visits with patients
    3.1.1 schedule labs & tests
3.2 prepare monthly calendar for each clinical trial
3.3 fax monthly calendar to Infusion Nurse
3.4 fax monthly calendar to Pharmacist

4.0 Perform Clinical duties

4.1 order lab work
4.2 prepare drug orders
    4.2.1 obtain primary investigator signature on drug orders
4.3 administer drugs
4.4 participate in pharmacokinetics
    4.4.1 prepare test-tube labels
    4.4.2 draw blood
    4.4.3 perform time sampling

4.4.4 measure drug absorption rate
4.5 perform follow-up on all labs
4.6 manage side effects
4.6.1 contact patient
4.6.2 record side effect(s)
4.6.3 treat side effect(s)
4.6.4 consult physician (as needed)
4.6.5 schedule physician visit (as needed)
4.7 schedule patient + physician follow-up visits

5.0 Monitor Patients

Goal: Assess and manage patient side effects

Constraints: Phase I clinical trials are designed to achieve maximum dose toxicity; the severity of side effects is the limiting factor.

5.1 participate in weekly review meeting
5.1.1 prepare patient information packet
5.1.2 review patient status
5.1.3 discuss problems
5.1.4 assess side effects
5.1.4.1 grade toxicities
5.1.4.2 note dose limiting factors
5.1.5 discuss patient referrals
5.1.6 discuss trial / study status
5.2 Assess disease stability
` 5.3 Assess tumor response

6.0 Manage Patient Data

Goal: Ensure the LCC is in compliance with clinical trial data reporting requirements (FDA, NCI, or drug sponsor).

6.1 review protocol mechanics
6.2 participate in monitoring visits
6.2.1 prepare patient data in required format
6.2.1.1 maintain flow sheets
6.2.1.2 document missed drug doses
6.2.1.3 review Case Report Form (CRF)
6.2.2 provide copies of CRF to monitoring organization
6.2.3 schedule monitoring visit

Entry for Domain Dictionary

Pharmacokinetics: movements of drugs within biological systems, as affected by uptake, distribution, elimination, and biotransformation.

Initial Concept Identification

Research Nurse
Patient
Case Report Forms
Phase I Clinical Trial Protocol
Patient Schedule
Patient Screening
Patient Enrollment
Patient Treatment
Side Effects Management
Pharmacokinetics